## Kaczmarek, Chris

From: Kaczmarek, Chris

**Sent:** Friday, October 03, 2014 11:31 AM

To: Taub, Cynthia; Goldberg, Seth; Allison\_Starmann@americanchemistry.com

Cc: Ross, Philip; Talbert, Stephanie (ENRD); Lewis, Susan; McIain, Jennifer; McIean, Kevin

Subject: RE: Confidential Settlement Communication re Draft Settlement Agreement

## Cynthia and Seth,

During our negotiations concerning settlement of the lawsuit ACC filed against the Agency over the Agency's promulgation of the data requirements contained in 40 CFR Part 158-W, ACC has raised a number of topics that it would like to discuss with the Antimicrobial Division (AD) within EPA's Office of Pesticide Programs (OPP). Specifically, ACC has indicated its desire to schedule meetings with AD to discuss the following:

- 1. the "potable water rinse" and related tolerance issues;
- the "incidental oral risk assessment" issue;
- 3. the "down the drain guidance" issue;
- 4. the "residue dissipation guidance" issue; and
- 5. what ACC has described somewhat amorphously as the "other risk assessment guidance" issues.

As EPA has previously stated, it is our view that none of these issues has anything to do with the scope and/or legality of the Part 158-W rulemaking or regulations; rather, EPA believes these issues are focused on how EPA will conduct its risk assessments going forward. Accordingly, EPA does not believe that any of these issues relate to or involve any alleged legal infirmity with the Part 158-W rule that ACC is challenging and are not, therefore, properly at issue in this lawsuit.

In addition to the topics identified above, ACC also has expressed a desire to schedule a meeting with AD to discuss the definition of fungicide in 40 CFR Part 158-W. While this definition does fall within the scope of the Part 158-W rulemaking/regulation, as EPA has previously pointed out to ACC, and as ACC has acknowledged, no comments were submitted by ACC or any other commenter on this specific definition or on the specific alleged problem that ACC has identified with this definition (i.e., the inclusion of the "pathogenic to man or other animals" language in the definition). As a result, EPA is also willing to schedule a conversation with ACC on this definition while EPA performs its obligations under the settlement agreement that the parties are seeking to execute.

Before initiating any of these discussions, however, and in recognition of the fact that these discussions will be taking place while the settlement agreement is either being finalized or while EPA subsequently performs its obligations under the settlement agreement, EPA will need for ACC to affirmatively acknowledge in writing (email is fine) that, should ACC seek to reopen the case based upon an alleged breach of the settlement agreement, it will not raise any of these issues in the context of pressing forward with its underlying lawsuit on the 158-W regulation.

Assuming that ACC will provide such an assurance in writing, and as we have previously discussed, EPA envisions ACC contacting AD within two weeks of the date of EPA's receipt of the ACC acknowledgment requested immediately above to initiate the scheduling of a discussion on the potable water rinse and related tolerance issues, and on the incidental oral risk assessment issue. In addition, and again as we have previously discussed, EPA envisions ACC contacting AD at some point after the settlement agreement has been executed to initiate the scheduling of a discussion or discussions on the remaining topics specifically identified above. As we previously agreed, the discussions on these remaining topics would be set up to take place anywhere from 2 to 6 months following finalization of the settlement agreement. In all cases, it is EPA's expectation that ACC will clarify, either at or in advance of any scheduled meetings, the specific matters within these broadly identified issue areas on which ACC would like to focus its discussions with EPA.

We look forward to hearing back from you and to initiating these discussions with ACC's member companies.

Sincerely, Chris

Chris E. Kaczmarek
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From: Talbert, Stephanie (ENRD) [mailto:Stephanie.Talbert@usdoj.gov]

Sent: Friday, October 03, 2014 11:03 AM

To: Taub, Cynthia; Goldberg, Seth; Allison\_Starmann@americanchemistry.com

Cc: Kaczmarek, Chris; Ross, Philip

Subject: Confidential Settlement Communication re Draft Settlement Agreement

Cynthia,

Attached please find a draft settlement agreement for your consideration. This draft represents what EPA and DOJ staff are willing to recommend to our respective management for formal approval. Chris will be sending the email regarding conversations between ACC and AD by separate cover. We look forward to discussing the Agreement with you.

Best regards,

Stephanie

Stephanie J. Talbert Attorney U.S. Department of Justice, ENRD Environmental Defense Section